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		Art Unit	1641
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# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

### Before the Board of Patent Appeals and Interferences

Appl. No.:

09/638,102

Filed:

August 11, 2000

Applicant:

David C. Schwartz

Title:

Chemical Screening System Using Strip Arrays

Art Unit:

1641

Examiner:

Davis, Deborah A.

Docket No.: 1512.112

## APPELLANT'S REPLY BRIEF ON APPEAL

MS Appeal Brief - Patents Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Appellant, David C. Schwartz, having received an Examiner's Answer in the aboveidentified patent application, hereby submits this Reply Brief.

#### I. REAL PARTY IN INTEREST

The real party in interest is the Wisconsin Alumni Research Foundation.

#### RELATED APPEALS AND INTERFERENCES II.

There are no related appeals or interferences.

#### III. STATUS OF CLAIMS

Claims 2, 5 - 7 9 - 13, and 35 are allowed. Claims 14 - 33 are withdrawn from consideration. Claims 41 and 43 - 52 have been rejected. Appeal is taken with respect to claims 41 and 43 - 52.

### IV. STATUS OF AMENDMENTS

No amendments were made in response to the final office action. All amendments have therefore been previously entered.

#### V. SUMMARY OF THE INVENTION

The invention recited in the claims under appeal is a kit for producing customized chemical sampling arrays. Chemical sampling arrays are arrays of different chemical sampling compounds arranged in a regular pattern. Each sampling compound in the array is selected to bond with a different substance that may be part of a material to be analyzed. These devices are used, for example, in genetic research, where the sampling compounds may be different oligonucleotides at least one of which is expected to hybridize with portions of a genetic material to be tested. Information about the make-up or other attributes of the genetic material may be determined by analyzing the locations of hybridization in the array.

In the prior art, chemical sampling arrays were developed either directly by producing planar arrays of different sampling compounds using masking techniques, or by placing sampling compounds on beads and then arranging the beads into arrays. Masking techniques for forming arrays, although effective, do not allow a user to vary the sample compounds in the array, and therefore do not provide sufficient flexibility for researchers to design experiments. Bead systems rectify the problem of flexibility. However, because the beads are extremely small, assembling the beads into arrays is mechanically very difficult and expensive.

In the present invention, different chemical sample compounds are provided at spaced intervals along a strip or filament constructed of a non-reactive substrate to produce a linear array. A library comprising a plurality of strips having various chemical sample compound arrays is then provided in a kit along with a support frame. A user can then arrange a subset of strips chosen from the library in the frame. By selecting among the strips, a user can construct a semi-customized array of chemical sample compounds in the frame. The present invention, therefore, provides a cost effective way of manufacturing custom arrays.

# VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Are claims 41, 43, 45 - 46, and 48 unpatentable under 35 U.S.C. Section 103(a) over Gross, U.S. Patent 4,867,946 in view of Zuk, U.S. Patent 4,281,061? Is claim 44 unpatentable over Gross in view of Zuk and further in view of Adams, U.S. Patent 6,156,494? Are claims 49 - 52 unpatentable over Gross in view of Zuk and further in view of Bentsen, U.S. Patent 6,372,895?

#### VII. ARGUMENT

1. Kit claims are proper in this application and properly supported by the specification.

The Examiner has indicated in the Examiner's Answer, that the limitations related to a "chemical screening kit" are not supported by the specification. This is counter to both current law and a clear reading of the specification.

It is well understood that the word "kit" and the phrase "chemical screening kit" need not be found in the specification to be used in the claims. As noted in MPEP 2163.02, second to last paragraph.

The subject matter of the claim need not be described literally (i.e., using the same terms or in <u>haec verba</u>) in order for the disclosure to satisfy the description requirement.

A kit claim is expressly recognized in *In re Venezia*, a case previously cited to the Examiner and acknowledged in the MPEP at 2173.05(g). In the *Venezia* case, issued as U.S.

Patent 4,099,021, the word "kit" was not used in the specification, but only in the amended claims. It is well established that "kit" claims are proper and that "kit" or similar phrase need not be found in the specification so long as a kit is actually described

Accordingly, the Examiner's rejection must be based not on the fact that "chemical screening kit" or "kit" is not found in the specification, but that the specification would not lead someone of ordinary skill in the art to recognize that a kit has been described.

In this regard, a dictionary definition of "kit" is a "set of parts to be assembled." Looking at the specification, it is clear that a kit of strips has been described. At page 4, lines 9-12, the application indicates:

[T]he strips are easily handled and identified and may be assembled into dense planar arrays with desired arbitrary row variations. By using strips, an improved tradeoff between mass production and flexibility is obtained. (page 4, lines 8 through 12).

One of ordinary skill in the art would recognize that the mass produced strips are a kit because they are "a set of parts" to be assembled into planar arrays of arbitrary row variations. Yet it is also clear that the reassembly and rearrangement of the strips of a kit is an essential benefit of the invention. The specification further says at page 4, lines 22-25,

Thus it is one object of the invention to facilitate the screening of chemical compounds against a large number of sample compounds in an efficient yet flexible way. Each strip may be manufactured in a batch including many other strips and, then separated from the batch and assembled to produce a variety of different arrays.

A person of ordinary skill in the art would recognize this language to be describing a kit or a set of parts in the form of strips that are assembled to produce a variety of different arrays. Importantly, the ability that a kit provides to conform to the needs of a particular instant, much after manufacturing, is clearly contemplated. Page 10, lines 7 through 17 of the specification describes:

Referring now to Fig. 4, it will be understood that the technique of assembling short lengths of the filaments 10 into an array 32 allows a wide variety of semi-custom arrays 32 to be created from a more limited set of standard filaments 10. In Fig. 4, the letters indicate different sampling compounds 14. The sequence of sampling compounds 14 of each row formed by a filament 10 will be defined by the set of standard filaments 10.

Nevertheless, the number of different arrays 32 will be equal to the mathematical combination of the number of different filament types, a far larger number. For example, from a library of 400 standard fibers, 10<sup>119</sup> different 200 fiber arrays 32 may be created. In this way, the use of filaments 10 to create an array 32, leverages a limited number of filament types into an extremely flexible variety of arrays 32. The arrays 32 may be assembled efficiently by robotic techniques or the like and may be verified by reading the identification markers 24 unique to each filament.

The Examiner 's refusal to acknowledge legitimate limitation of the current claims appears to have caused the Examiner to ignore not only the limitation of the invention providing a "kit," but also the need for a "library of strips" with different linear arrays of chemically reactive substances, from which a "subset of the library" may be fit into a frame for exposure to a material to be screened.

It is clear that none of the references cited, alone or in combination, teach constructing semi-custom array of reactive substances as claimed, nor does the Examiner contend otherwise, apparently relying on a refusal to recognize express portions of the claims.

2. <u>Identical strips having multiple chemicals are not "different linear arrays of chemical</u> compounds" but identical linear arrays of chemical compounds.

The Examiner states that <u>Gross</u> "teaches a library of test strips having different linear arrays of chemical compounds along each test strip" It is clear, however, that the strips of <u>Gross</u> are not different linear arrays of chemical compounds but the identical linear arrays of compounds.

Gross takes a number of identical strips, individually exposes them to urine, then analyzes them together, as befits them being identical arrays. The Examiner's oblique interpretation of this claim limitation is counter to the plain and ordinary meaning of "different linear array", defies the specification of the present invention, and cannot be reconciled with the claim language requiring a support frame for receiving and holding "different combinations" of a subset of the library of strips. How can the identical linear arrays of Gross be arranged in different combinations?

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3. A prior art reference cannot teach or suggest a modification that would render the reference unsuitable for its intended purpose.

The Examiner suggests that it is of no significance that <u>Gross</u> expressly teaches that the urine test strips must be exposed to urine of different individual patient's individually before the test strips are placed on a common frame for analysis, because it is always obvious to reverse the

order of a multi-step process. Yet, if the urine test strips of Gross were placed on the common

frame before exposure to patient urine, it would be impossible to identify which patient results

were associated with which strip, rendering Gross inoperative. Gross, therefore cannot suggest

the modification proposed by the Examiner necessary to meet the limitations of the present

invention.

VIII. CONCLUSION

The limitations of the claims are proper under law and supported by the specification.

Gross and Zuk in combination still do not teach all of the elements of claims 41 and 43 - 52.

Moreover, there is no reasonable motivation to combine these references. Therefore, the

Applicants respectfully request that the rejection of claims 41 and 43 - 52 be overturned.

Respectfully submitted,

DAVID C. SCHWARTZ

Dated: July 28, 2006

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#### APPENDIX A

#### Listing of Claims

Claim 1. (canceled)

Claim 2. (previously presented): The semi-custom array for chemical screening of claim 35 wherein the strips have a length taken along the longitudinal axis of at least ten times the maximum cross-sectional dimension of the strips taken across the longitudinal axis.

Claims 3 - 4. (canceled)

- Claim 5. (previously presented): The semi-custom array for chemical screening of claim 35 wherein the non-reactive strips are glass fibers.
- Claim 6. (previously presented): The semi-custom array for chemical screening of claim 35 wherein the support frame holds the strips transversely spaced in parallel relationship.
- Claim 7. (previously presented): The semi-custom array for chemical screening of claim 35 wherein the support frame holds the strips transversely spaced along two perpendicular axes.

Claim 8. (canceled)

- Claim 9. (previously presented): The semi-custom array for chemical screening of claim 35 wherein the strips include recessed portions receiving the chemically reactive substances.
- Claim 10. (previously presented): The semi-custom array for chemical screening of claim 35 wherein the strips include a marker allowing the strips to be distinguished.
- Claim 11. (previously presented): The semi-custom array for chemical screening of claim 10 wherein the marker is selected from the group of printing and fluorescent material.
- Claim 12. (previously presented): The semi-custom array for chemical screening of claim 35 wherein the strips include a marker allowing a given end of the strip to be identified.
- Claim 13. (previously presented): The semi-custom array for chemical screening of claim 35 wherein the marker is selected from the group of printing and fluorescent material.

- Claim 14. (withdrawn): A chemical screening apparatus comprising a strip of a nonreactive substrate extending along a longitudinal axis and supporting, spaced along that longitudinal axis, a linear array of different, oligonucleotides exposed on a surface of the strip.
- Claim 15. (withdrawn): The chemical screening apparatus of claim 14 wherein the strip has a length taken along the longitudinal axis of at least ten times the maximum cross-sectional dimension of the strip taken across the longitudinal axis.
- Claim 16. (withdrawn): The chemical screening apparatus of claim 14 wherein the nonreactive strip is a glass fiber.
- Claim 17. (withdrawn): The chemical screening apparatus of claim 14 wherein the strips include isolating bands of a chemically repellant coating between the chemically reactive substances.
- Claim 18. (withdrawn): The chemical screening apparatus of claim 14 wherein the strips include recessed portions receiving the chemically reactive substances.
- Claim 19. (withdrawn): The chemical screening apparatus of claim 14 wherein the strips include a marker allowing the strips to be distinguished.
- Claim 20. (withdrawn): The chemical screening apparatus of claim 14 wherein the marker is selected from the group of printing and fluorescent material.
- Claim 21. (withdrawn): The chemical screening apparatus of claim 14 wherein the strips include a marker allowing a given end of the strip to be identified.
- Claim 22. (withdrawn): The chemical screening apparatus of claim 1 wherein the marker is selected from the group of printing and fluorescent material.
- Claim 23. (withdrawn): A method of manufacture of strips of a non-reactive substrate extending along a longitudinal axis and supporting, spaced along that longitudinal axis, a linear array of different, chemically reactive substances exposed on a surface of the strip comprising the steps of;
- (a) affixing the strips in a frame to be transversely spaced in parallel relationship in a plane to expose at a plane, surface locations for the chemically reactive substances;
  - (b) immersing the frame in a sequence of component solutions;

- (c) light activating the bonding of a substance of the component solution with the strips at a subset of the locations for each component solution; and
  - (d) releasing the strips from the frame.

Claim 24. (withdrawn): A method of manufacture of strips of a non-reactive substrate extending along a longitudinal axis and supporting, spaced along that longitudinal axis, a linear array of different, chemically reactive substances exposed on a surface of the strip comprising the steps of;

- (a) positioning the strip to have different longitudinal portions positioned in adjacent volumes holding different component solutions;
- (b) light activating the bonding of a substance of at least one of the component solutions with the strip at a location for at least one of the chemically reactive substances;
  - (c) repositioning the strip within the volumes of different component solutions; and
  - (d) repeating steps (b) and (c) to create chemically reactive substances at the locations.
- Claim 25. (withdrawn): The method of claim 24 wherein multiple strips are simultaneously positioned within the adjacent volumes to have light activated bonding of the component solution.
- Claim 26. (withdrawn): The method of claim 24 wherein the volumes are separated by a multiple of the separation of the locations of the chemically reactive substances.
- Claim 27. (withdrawn): The method of claim 26 wherein the strip is formed in a continuous loop to circulate through the volumes.

Claim 28. (withdrawn): A method of manufacture of strips of a non-reactive substrate extending along a longitudinal axis and supporting, spaced along that longitudinal axis, a linear array of different, chemically reactive substances exposed on a surface of the strip comprising the steps of;

- (a) positioning a plurality of strips to pass through a volume bracketing a segment of the strips;
- (b) fill the volume with component solution bonding onto the segments a portion of the chemically reactive substances;
  - (c) flush the volume of component solution;
- (d) repositioning at least some of the strip within the volumes so that different segments are subtended; and

- (e) repeating steps (b) and (c) with different chemical solutions to create the chemically reactive substances at the locations.
- Claim 29. (withdrawn): The method of claim 28 wherein the strips are independently repositioned so that each strip may have different chemically reactive substances with respect to the others.
- Claim 30. (withdrawn): A method of manufacture of strips of a non-reactive substrate extending along a longitudinal axis and supporting, spaced along that longitudinal axis, a linear array of different, chemically reactive substances exposed on a surface of the strip comprising the steps of;
- (a) affixing the strips in a frame to be transversely spaced in parallel relationship in a plane to expose at a plane, surface locations for the chemically reactive substances;
  - (b) placing a mask material over the plane exposing a selected subset of locations;
  - (c) immersing the frame in a sequence of component solutions;
- (d) repeating steps (b) and (c) for a plurality of masks and component solutions to create the different chemically reactive substances; and
  - (e) releasing the strips from the frame.
- Claim 31. (withdrawn): A method of manufacture of beads of a non-reactive substrate supporting different, chemically reactive substances exposed on a surface of the strip comprising the steps of:
- (a) preparing strips of a non-reactive substrate extending along a longitudinal axis and supporting, spaced at locations along that longitudinal axis, a linear array of different, chemically reactive substances exposed on a surface of the strip by repeated exposure of the locations to different chemical materials in a predefined sequence; and
  - (b) cutting the strip between the locations to produce the beads.
- Claim 32. (withdrawn): A method of screening chemical materials comprising the steps of:
- (a) preparing at least two different strips of a non-reactive energy conductive substrates extending along a longitudinal axis and supporting, spaced along that longitudinal axis, a linear array of different, chemically reactive substances exposed on a surface of the strip;
  - (b) arranging the strips to cross at a read-out site;

- (c) applying energy to at least one of the strips to promote an energetic interaction with a chemically reactive substance at the read-out site; and
- (d) detecting energy at least one of the strip to detect the energetic interaction at the read out site.
- Claim 33. (withdrawn): A method of promoting localized chemical reactions comprising the steps of:
- (a) preparing least two different strips of a non-reactive energy conductive substrates extending along a longitudinal axis and supporting, spaced along that longitudinal axis, a linear array of different, chemically reactive substances exposed on a surface of the strip;
  - (b) arranging the strips to cross at a promotion site;
- (c) applying energy to at least one of the strips to promote an energetic interaction with a chemically reactive substance at the promotion site causing the localized chemical reaction.

Claim 34. (canceled)

- Claim 35. (previously presented): A semi-custom array for chemical screening comprising:
- (a) at least two different strips of a non-reactive substrate extending along a longitudinal axis and supporting, spaced along that longitudinal axis, a linear array of different, chemically reactive substances exposed on a surface of the strip; and
- (b) a support frame for receiving and holding the strips for mutual exposure to a material to be screened wherein the strips include isolating bands of a chemically repellant coating between the chemically reactive substances.

Claims 36 40. (canceled)

Claim 41. (previously presented): A chemical screening kit comprising:

- (a) a library of strips of a non-reactive substrate extending along a longitudinal axis, each strip supporting, spaced along that longitudinal axis, different linear arrays of chemically reactive substances exposed on a surface of the strip; and
- (b) a support frame for receiving and holding different combinations of a subset of the library of strips for mutual exposure to a material to be screened;

whereby a semi-custom array of reactive substances may be created.

Claim 42. (canceled)

- Claim 43. (previously presented): The chemical screening kit of claim 41 wherein the strips have a length taken along the longitudinal axis of at least ten times the maximum cross-sectional dimension of the strip taken across the longitudinal axis.
- Claim 44. (previously presented): The chemical screening kit of claim 41 wherein the non-reactive strips are glass fibers.
- Claim 45. (previously presented): The chemical screening kit of claim 41 wherein the support frame holds the strips transversely spaced in parallel relationship.
- Claim 46. (previously presented): The chemical screening kit of claim 41 wherein the support frame holds the strips transversely spaced along two perpendicular axes.
- Claim 47. (previously presented): The chemical screening kit of claim 41 wherein the strips include isolating bands of a chemically repellant coating between the chemically reactive substances.
- Claim 48. (previously presented): The chemical screening kit of claim 41 wherein the strips include recessed portions receiving the chemically reactive substances.
- Claim 49. (previously presented): The chemical screening kit of claim 41 wherein the strips include a marker allowing the strips to be distinguished.
- Claim 50. (previously presented): The chemical screening kit of claim 41 wherein the marker is selected from the group of printing and fluorescent material.
- Claim 51. (previously presented): The chemical screening kit of claim 41 wherein the strips include a marker allowing a given end of the strip to be identified.
- Claim 52. (previously presented): The chemical screening kit of claim 41 wherein the marker is selected from the group of printing and fluorescent material.

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# EVIDENCE APPENDIX

No additional evidence is provided.

# RELATED PROCEEDINGS APPENDIX

There are no related proceedings.